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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,187	06/02/2005	Emma R. Parmee	21208P	1269
<div>210 7590 09/24/2007</div> <div>MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907</div> <div>EXAMINER MURRAY, JEFFREY H</div> <div>ART UNIT 1624 PAPER NUMBER</div> <div>MAIL DATE 09/24/2007 DELIVERY MODE PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,187	Applicant(s) PARMEE ET AL.	
	Examiner Jeffrey H. Murray	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/28/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. The compound or composition of formula (I), according to Claims 1-5, 9-20 wherein $X = CH_2$, a and $b = 0$, and Y is a seven-membered or larger nitrogen containing heterocyclic ring.
- II. The compound or composition of formula (I), according to Claims 1-5, 19-20 wherein $X = CH_2$, a and $b = 0$, and Y is a six-membered heterocyclic ring with at least 2 heteroatoms, at least one being nitrogen.
- III. The compound or composition of formula (I), according to Claims 1-20 wherein $X = CH_2$, a and $b = 0$, and Y is a six-membered heterocyclic ring with one nitrogen.
- IV. The compound or composition of formula (I), according to Claims 1-5, 19-20 wherein $X = CH_2$, a and $b = 0$, and Y is a five- or four-membered heterocyclic ring with at least one nitrogen.
- V. The compound or composition of formula (I), according to Claims 1-5, 19-20 wherein $X = CH_2$, a and $b = 0$, and Y is a sulfur containing ring

heterocyclic ring with no nitrogen ring members or an oxygen containing ring with no sulfur or nitrogen ring members.

- VI. The compound or composition of formula (I), according to Claims 1-5, 19-20 wherein $X = CH_2$, a and $b = 0$, and Y is a cycloalkyl ring.
- VII. The compound or composition of formula (I), according to Claims 1-3, 5, 9-19-20 wherein $X = C(=O)$, a and $b = 0$, and Y is a seven-membered or larger nitrogen containing heterocyclic ring.
- VIII. The compound or composition of formula (I), according to Claims 1-3, 5, 9-19-20 wherein $X = C(=O)$, a and $b = 0$, and Y is a six-membered heterocyclic ring with at least 2 heteroatoms, at least one being nitrogen.
- IX. The compound or composition of formula (I), according to Claims 1-3, 5-20 wherein $X = C(=O)$, a and $b = 0$, and Y is a six-membered heterocyclic ring with one nitrogen.
- X. The compound or composition of formula (I), according to Claims 1-3, 5, 9-19-20 wherein $X = C(=O)$, a and $b = 0$, and Y is a five- or four-membered heterocyclic ring with at least one nitrogen.
- XI. The compound or composition of formula (I), according to Claims 1-3, 5, 9-19-20 wherein $X = C(=O)$, a and $b = 0$, and Y is a sulfur containing ring heterocyclic ring with no nitrogen ring members or an oxygen containing ring with no sulfur or nitrogen ring members.
- XII. The compound or composition of formula (I), according to Claims 1-5, 19-20 wherein $X = C(=O)$, a and $b = 0$, and Y is a cycloalkyl ring.

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- XIII. The compound or composition of formula (I), according to Claims 1-5, 9-19-20 wherein $X = CH_2$, a or $b = 1$, and Y is a seven-membered or larger nitrogen containing heterocyclic ring.
- XIV. The compound or composition of formula (I), according to Claims 1-5, 19-20-20 wherein $X = CH_2$, a or $b = 1$, and Y is a six-membered heterocyclic ring with at least 2 heteroatoms, at least one being nitrogen.
- XV. The compound or composition of formula (I), according to Claims 1-20 wherein $X = CH_2$, a or $b = 1$, and Y is a six-membered heterocyclic ring with one nitrogen.
- XVI. The compound or composition of formula (I), according to Claims 1-5, 19-20 wherein $X = CH_2$, a or $b = 1$, and Y is a five- or four-membered heterocyclic ring with at least one nitrogen.
- XVII. The compound or composition of formula (I), according to Claims 1-5, 19-20-20 wherein $X = CH_2$, a or $b = 1$, and Y is a sulfur containing ring heterocyclic ring with no nitrogen ring members or an oxygen containing ring with no sulfur or nitrogen ring members.
- XVIII. The compound or composition of formula (I), according to Claims 1-20 wherein $X = CH_2$, a or $b = 1$, and Y is a cycloalkyl ring.
- XIX. The compound or composition of formula (I), according to Claims 1-3, 5, 9-20 wherein $X = C(=O)$, a or $b = 1$, and Y is a seven-membered or larger nitrogen containing heterocyclic ring.

- XX. The compound or composition of formula (I), according to Claims 1-3, 5, 9-20 wherein $X = C(=O)$, a or $b = 1$, and Y is a six-membered heterocyclic ring with at least 2 heteroatoms, at least one being nitrogen.
- XXI. The compound or composition of formula (I), according to Claims 1-3, 5-20 wherein $X = C(=O)$, a or $b = 1$, and Y is a six-membered heterocyclic ring with one nitrogen.
- XXII. The compound or composition of formula (I), according to Claims 1-3, 5, 9-20 wherein $X = C(=O)$, a or $b = 1$, and Y is a five- or four-membered heterocyclic ring with at least one nitrogen.
- XXIII. The compound or composition of formula (I), according to Claims 1-3, 5, 9-20 wherein $X = C(=O)$, a or $b = 1$, and Y is a sulfur containing ring heterocyclic ring with no nitrogen ring members or an oxygen containing ring with no sulfur or nitrogen ring members.
- XXIV. The compound or composition of formula (I), according to Claims 1-5, 19-20 wherein $X = C(=O)$, a or $b = 1$, and Y is a cycloalkyl ring.
- XXV. The compound or composition of formula (I), according to Claims 1-20, not previously described in Groups I-XX.
- XXVI-
L The method of treating type 2 diabetes mellitus using a compound or composition of formula (I) from Groups I-XXV, according to Claim 21.

2. The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the claims is a cyclic urea of Formula (I). Prior art exists which causes the core structure in the current application to lack a special technical feature. The core structure here is a cyclic urea of Formula (I) in the form of an imidazolidin-2-one with a *p*-benzylamide attached to the 1-nitrogen. This core structure is seen in numerous patents and papers. For example, Lee, et. al., (US 6384061) teaches an imidazolidin-2,4-dione where the R¹ is an alkyl imidazolyl group, R2 and R7 are hydrogen, and the 5-carbon is substituted with a methyl and naphthyl group. Therefore the feature linking the claims does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the art.

Accordingly, Groups I-XXII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

3. This application contains claims directed to the following patentably distinct species: all the various compounds of Claim 19. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or

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employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. During a telephone conversation with Richard Billups on September 12, 2007, a provisional election was made without traverse to prosecute the invention of Group XVIII, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claim 21 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

6. Acknowledgment is made of Applicant's claim for domestic priority. This application is U.S. Application No. 10/537,187, filed June 2, 2005, which is a national stage entry of PCT/US03/38590, filed November 26, 2003, which claims the benefit of U.S. Provisional Application No. 60/430,799, filed December 04, 2002.

Specification

7. The use of the trademark PRISM has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any of the errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 112, 1st

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-18 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds where R¹ is an alkyl, cycloalkyl, or optionally substituted phenyl or benzyl and Y being a 4-*t*-butylcyclohexyl group does not reasonably provide enablement for all other compounds and residue groups listed within the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

11. The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation. (*United States v. Teletronics Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors (See *Ex parte Forman* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988)).

These factors include the following:

1) *Amount of guidance provided by Applicant.* While the Applicant has demonstrated within the application how to make numerous compounds, only compounds with R¹ as an alkyl, cycloalkyl, or optionally substituted phenyl or benzyl and Y as a *t*-butylcyclohexyl group. Claim 1 is massive, and only a small fraction of these "potential" compounds are discussed, and their synthesis shown. No reference is made as to how to synthesize any compounds that contain an R¹ other than those listed, or any other type of cycloalkyl group other than the *t*-butylcyclohexyl group.

2) *Unpredictability in the art.* It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. (USPQ 18, 24 (CCPA 1970). See *In re Fisher*, 427 F.2d 833, 839, 166.

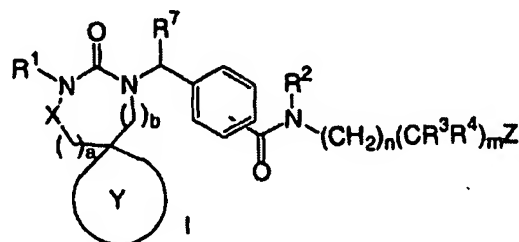
3) *Number of working examples.* Of the thousands of spirocyclic urea compounds that could exist in the applicant's claims, applicant has provided only

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approximately seven working example compounds that do not fall outside of the scope described previously.

This is a miniscule fraction of the number of compounds that exist in the broad Claim 1.

4) *Scope of the claims.* The scope of the claims involve all of the thousands of compounds of general formula I:



Thus, the scope of claims is very broad.

5) *Nature of the invention.* The nature of this invention relates generally to triazolo-pyrimidines, a method for their preparation and their use for combating undesirable micro-organisms. The invention also relates to new intermediate products and processes for their preparation.

6) *Level of skill in the art.* The artisan using Applicants invention would be a chemist with a Ph.D. degree, and having several years of bench experience.

MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That

Allowable Subject Matter

12. Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 19 would be allowable because the Claim specifically contains compounds that are not defined in any of the prior art. The limitation not seen in the prior art is the presence of a spirocycloalkyl group attached to the tetrahydropyrimidin-2(1H)-one ring, in particular a 4-*t*-butylcyclohexyl group present to make substituted 1,3-diazaspiro[5.5]-undecan-2-one derivatives.

Conclusion

13. Claims 1-18 and 20 are rejected.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is (571) 272-9023. The examiner can normally be reached on Mon-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, James O. Wilson can be reached at 571-272-9023. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a US PTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JHM



James O. Wilson
Supervisory patent Examiner
Art Unit 1624